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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/774,826

02/09/2004

Barry N. Gellman

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ROPES & GRAY LLP  
PATENT DOCKETING 39/41  
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BOSTON, MA 02110-2624

EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/774,826	<b>Applicant(s)</b> GELLMAN ET AL.	
	<b>Examiner</b> John P. Lacyk	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 163-167,170,171,173-180,182-188,190-195,197,198 and 200-210 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 175-180,182-188,190-195,197-198,200-206,208-210 is/are allowed.
- 6) ☒ Claim(s) 163-167,170,171,173,174 and 207 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 163, 173-174 and 207 are rejected under 35 U.S.C. 102(a) as being anticipated by Claren et al (5,899,909).

Claren et al discloses a mesh tape or sling (26) that is covered by a sheath or pouch (34) that is removable once the tape is properly positioned (column 4, line 30-column 5, line 20). The sheath can cover as much of the tape as desired to protect the tape during insertion.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 163-167, 170-171, 173-174, 203 and 207 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benderev et al in view of Norris et al and Claren et al.

Benderev et al discloses a device for treating incontinence having a shaft that has a curved portion and a distal end (Figures 1 and 1a; column 2, lines 34-36 and column 5, lines 7-9) and a “sling assembly” or suture for being received in the distal end of the

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shaft. Benderev et al teaches the claimed system except for the "sling assembly" specifically being a flat shape. Norris et al teaches a sling assembly for use in treating incontinence and teaches that it is well known to use a sling that has a flat shape (see Figure 2 and column 2 under "Technique"). A modification of Benderev et al such that the suture used as a sling is substituted with a flat shaped sling as taught by Norris et al would have been obvious to one skilled in the art since the flat shaped sling would provide more surface area to allow for added support to treat incontinence. Therefore a modification of Benderev et al would have been obvious since this would be the mere substitution of one known type of sling to treat incontinence for another and would allow for added support and a more evenly distributed force on the body. Benderev et al further teaches the use of a channel (130) on the distal end of the shaft (Figure 2) the is used to attach to the suture in a releasable manner that can be locked or unlocked (column 5, line 60-column 6, line 36). This is considered to be a "interlocking mating structure" between the shafts distal end and the suture or sling assembly.

Benderev et al and Norris et al teach the claimed device except for the use of a pouch over a portion of the sling assembly. Claren et al, as discussed above, discloses a similar sling device having mesh tape or sling (26) that is covered by a sheath or pouch (34) that is removable once the tape is properly positioned. Therefore a modification of the Benderev et al and Norris et al sling to include a sheath or pouch would have been obvious in view of the teachings of Claren et al in order to protect the sling while being inserted into the proper position within the body.

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Claims 175-180, 182-188, 190-195, 197-198, 200-2002, 204-206, 208-210 are allowed.

Applicant's arguments with respect to claims 163, 173-174 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/  
Primary Examiner, Art Unit 3735